IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	**Redacted - Public Version** C.A. No. 21-1317-GBW-SRF

ALCON'S RESPONSES TO SIGHT'S CONCISE STATEMENTS OF FACTS AND ALCON'S ADDITIONAL CONCISE STATEMENT OF FACTS

Pursuant to Paragraph 14(b) of the Scheduling Order (D.I. 93), Alcon submits its responses to Sight's concise statements of facts ("Resp. SOF") and its additional concise statement of facts with its answering brief to Sight's motions for summary judgment:

1. Response to Sight's Concise Statement of Facts in Support of its Summary Judgment Motion No. 1 ("Resp. SOF1") (Ex. 1).

2. Response to Sight's Concise Statement of Facts in Support of its Summary Judgment Motion No. 2 ("Resp. SOF2") and Additional Concise Statement of Facts in Support of Alcon's Answering Brief ("Add'l SOF2") (Ex. 2).

3. Response to Sight's Concise Statement of Facts in Support of its Summary Judgment Motion No. 3 ("Resp. SOF3") and Additional Concise Statement of Facts in Support of Alcon's Answering Brief ("Add'l SOF3") (Ex.3).

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Dated: November 2, 2023

Exhibit 1

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ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 1

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I. ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 1

1. Undisputed.

2. Disputed. The entirety of Hydrus is not a "support" under the Court's construction. D.I. 287 at 1. Alcon's expert, Dr. Iwach, opines that a portion of Hydrus's inlet is not a "support" and that Sight's expert, Dr. Downs, fails to explain how certain other portions of Hydrus meet the "support" limitation. *See* D.I. 292-14 at 42-49 (¶¶ 96-105). At least a portion of Hydrus is not in Schlemm's canal and therefore cannot be a "support" for Schlemm's canal. *Id.* at 42-45 (¶¶ 96-98). Sight's position that Hydrus is a "support" conflicts with its own positions regarding prior art references, which it claims do not disclose supports despite being designed to hold open Schlemm's canal when implanted. *Compare* D.I. 298-65 (Sight's Interrogatory No. 8 Resp.) at 19-20 *with* Ex. 26, Gharib ¶ 60 ("The shape of the end cross-section 35 is to provide a stenting capability."); Ex. 28, Lynch '334 ¶ 51 ("[S]ized and shaped to be circumferentially received within a portion of Schlemm's canal."); Ex. 24, Grieshaber-646 at 2:10-15 ("[T]he object is characterized in that the canal of Schlemm…is supported by appropriate means implanted in the expanded lumen of the canal of Schlemm and thus permanently held in an expanded position."); Ex. 32, Tu '052 at 11:2-3 ("[O]utflow section has an open trough for stenting purposes."); Ex. 30, Shadduck ¶ 42 ("The stent 100A has a … second expanded cross-sectional shape (FIG. 3B) for retracting or expanding the targeted tissue."); Ex. 31, Stegmann ¶¶ 10, 41 ("The implant may be provided with an expanded tip or cross-sectional shape to dilate the canal….[T]he tensioning elements [of the implant] may be designed to…provide a secondary expansion force to separate the walls of the canal or to dilate the canal."); Ex. 25, Neuhann at 3:61-64 ("This stent serves the purpose of spreading the trabecular formations on an internal side and hence reducing the outflow obstruction."); and Ex. 35, Samuelson2 ("iStent has been shown to improve aqueous outflow by

means of a patent channel created through the trabecular meshwork into Schlemm's canal."). It is undisputed that ***portions*** of the Hydrus are designed to hold open Schlemm's canal when implanted. For example, it is undisputed that FIG. 2(a) of D.I. 295-34 (SGHT0168157) shows a "[h]istological ***section*** of the Hydrus scaffold window ***region*** in situ showing SC dilation" (emphases added).

3. Undisputed, but immaterial. The term "device" only appears in the preamble of some Asserted Claims in the '482 and '443 Patents, and the preamble is not limiting. D.I. 298-1, '482 at 18:12, 19:35; D.I. 298-2, '443 at 18:12. Sight never asked the Court to construe any of the preamble terms of the Asserted Patents as limiting. *See* D.I. 90 (Joint Claim Construction Chart); D.I. 118 (Joint Claim Construction Brief).

4. Undisputed, but immaterial. The term "reducing intraocular pressure" only appears in the preamble of some Asserted Claims in the '482, '443, '361, and '328 Patents, and the preamble is not limiting. D.I. 298-1, '482 at 20:59; D.I. 298-2, '443 at 18:12, 20:41; D.I. 298-3, '361 at 18:33; D.I. 298-5, '328 at 18:40. Sight never asked the Court to construe any of the preamble terms of the Asserted Patents as limiting. *See* D.I. 90 (Joint Claim Construction Chart); D.I. 118 (Joint Claim Construction Brief).

5. Undisputed. Alcon has moved, however, to exclude Dr. Downs' testimony under his new construction of the "fenestration" term. D.I. 294 at 26.

6. Undisputed.

7. Undisputed.

8. Undisputed.

9. Undisputed that Hydrus is composed of nitinol, which is a shape-memory alloy that "has been used extensively in a variety of implantable devices for its proven properties of flexibility, strength, and biocompatibility." D.I. 292-2 at IVANTIS_SS_00041120.

10. Disputed. Hydrus is not laser cut "to form an arcuate support;" [redacted] Also disputed because the entirety of Hydrus is not "an arcuate support" for the reasons above in Resp. SOF1 ¶ 2. Alcon has also moved to exclude Dr. Downs' testimony under his new construction of the "arcuate member" term. D.I. 294 at 24.

11. Undisputed.

12. Disputed. There is no evidence of the amount of surface area the Hydrus contacts when implanted and disposed with the lumen of Schlemm's canal. Dr. Downs admitted that "there would be no way to calculate" the actual surface area contact a support makes when implanted, "[i]t would differ from – in every person," "it's incalculable," and there would be "all kinds of craziness" trying to make the calculation. D.I. 119-20, 120:19-121

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Exhibit 2

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FOR THE DISTRICT OF DELAWARE

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ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 2

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I. ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 2

1. Undisputed.

2. Disputed. The Hydrus does not have a "cross-sectional diameter," it has an elliptical cross-sectional shape with a major and minor axis of 292 micrometers and 185 micrometers, respectively. D.I. 292-18 (IVANTIS_SS_00056891).

3. Undisputed.

4. Disputed to the extent Sight contends that fluid actually flows across the trabecular meshwork and then through the windows when Hydrus is implanted. *See* D.I. 301 ¶¶ 7-8 (a POSA would not be able to determine flow of fluid through trabecular meshwork *in vivo*); D.I. 298-19 ¶ 109; Ex. 1, Iwach Rpl. Rep. ¶ 165 (opining that [redacted] and that dye study results "are not necessarily indicative of how aqueous humor flows *in vivo*"), ¶ 167 (opining that tracer studies were performed on healthy cadaver eyes not representative of *in vivo* flow in glaucomatous eyes and that authors did not conclude that there was flow across the trabecular meshwork when Hydrus was implanted), ¶ 168 (describing Gulati study that found no significant efficacy difference between an 8 mm version of Hydrus compared to a 15 mm version of Hydrus with more window regions), ¶¶ 169-172 (rebutting Dr. Downs' opinion that the cross-sectional shape of Hydrus creates pressure differential to promote flow across the trabecular meshwork because Dr. Downs makes incorrect assumptions and cherry-picks evidence); Ex. 37 (IVANTIS_SS_00471212) at 471214 (Sight's Chief Medical Officer stating that "we do not know how fluid flows in the trabecular meshwork or the collector channels and we do not have a way to follow outflow."); Ex. 36 (IVANTIS_SS_00344684) at 689-690 (study concluding that 15 mm version of Hydrus showed similar efficacy compared to 8 mm

version despite having more openings abutting the trabecular meshwork, suggesting fluid flows through Hydrus bypass inlet instead of through the trabecular meshwork); D.I. 298-18, Tanna Rpl. Rep ¶ 537 (opining that "the volume of 'aqueous outflux' per minute through the support itself cannot be measured *in vivo* and one could not measure the amount of transmural or longitudinal flow a particular device blocks").

5. Disputed. Sight's expert has contended that words like "operates to" or "enable flow" are equivalent to fluid flow actually occurring across the meshwork and then through the windows when Hydrus is implanted. *See, e.g.*, D.I. 298-23, 9/22 Downs Tr. 65:1-69:1. Such a determination is not possible. *See* D.I. 301 ¶¶ 7-8 (a POSA would not be able to determine flow of fluid through trabecular meshwork *in vivo*); D.I. 298-19 ¶ 109; Ex. 1, Iwach Rpl. Rep. ¶ 165 (opining that [redacted] and that dye study results "are not necessarily indicative of how aqueous humor flows *in vivo*"), ¶ 167 (opining that tracer studies were performed on healthy cadaver eyes not representative of *in vivo* flow in glaucomatous eyes and that authors did not conclude that there was flow across the trabecular meshwork when Hydrus was implanted), ¶ 168 (describing Gulati study that found no significant efficacy difference between an 8 mm version of Hydrus compared to a 15 mm version of Hydrus with more window regions), ¶¶ 169-172 (rebutting Dr. Downs' opinion that the cross-section shape of Hydrus creates pressure differential to promote flow across the trabecular meshwork because Dr. Downs makes incorrect assumptions and cherry-picks evidence); Ex. 37 (IVANTIS_SS_00471212) at 471214 (Sight's Chief Medical Officer stating that "we do not know how fluid flows in the trabecular meshwork or the collector channels and we do not have a way to follow outflow"); Ex. 36 (IVANTIS_SS_00344684) at 689-690 (study concluding that 15 mm

version of Hydrus showed similar efficacy compared to 8 mm version despite having more openings abutting the trabecular meshwork, suggesting fluid flows through Hydrus bypass inlet instead of through the trabecular meshwork); D.I. 298-18, Tanna Rpl. Rep ¶ 537 (opining that "the volume of 'aqueous outflux' per minute through the support itself cannot be measured *in vivo* and one could not measure the amount of transmural or longitudinal flow a particular device blocks").

6. Undisputed.

7. Disputed. Perfusion dye studies do not provide site-specific flow analysis. [redacted] Additionally, neither dye studies nor tracer studies provide evidence of flow through the trabecular meshwork *in vivo*. *See* D.I. 301 ¶¶ 7-8 (a POSA would not be able to determine flow of fluid through trabecular meshwork *in vivo*); D.I. 298-19 ¶ 109; Ex. 1, Iwach Rpl. Rep. ¶ 165 (opining that [redacted] and that dye study results "are not necessarily indicative of how aqueous humor flows *in vivo*"), ¶ 167 (opining that tracer studies were performed on healthy cadaver eyes not representative of *in vivo* flow in glaucomatous eyes and that authors did not conclude that there was flow across the trabecular meshwork when Hydrus was implanted), ¶ 168 (describing Gulati study that found no significant efficacy difference between an 8 mm version of Hydrus compared to a 15 mm version of Hydrus with more window regions), ¶¶ 169-

172 (rebutting Dr. Downs' opinion that the cross-sectional shape of Hydrus creates pressure differential to promote flow across the trabecular meshwork because Dr. Downs makes incorrect assumptions and cherry-picks evidence); Ex. 37 (IVANTIS_SS_00471212) at 471214 (Sight's Chief Medical Officer stating that "we do not know how fluid flows in the trabecular meshwork or the collector channels and we do not have a way to follow outflow"); Ex. 36 (IVANTIS_SS_00344684) at 689-690 (study concluding that 15 mm version of Hydrus showed similar efficacy compared to 8 mm version despite having more openings abutting the trabecular meshwork, suggesting fluid flows through Hydrus bypass inlet instead of through the trabecular meshwork); D.I. 298-18, Tanna Rpl. Rep ¶ 537 (opining that "the volume of 'aqueous outflux' per minute through the support itself cannot be measured *in vivo* and one could not measure the amount of transmural or longitudinal flow a particular device blocks").

8. Disputed. Sight purports to suggest that this study [redacted]

9. Disputed. The patents asserted in *Glaukos Corp. v. Ivantis, Inc.*, No. 8:18-cv-0620-JVS-JDE (C.D. Cal. 2018) involved different claims and claim terms. In that litigation, Dr. Tanna provided rebuttal expert opinions responding to Glaukos' expert's infringement opinions. For one of the Glaukos patents' claim terms, which recited "by-directional fluid flow," Dr. Tanna opined

that the Hydrus does not meet the limitation because Hydrus ***impedes*** axial flow (*i.e.*, flow across the trabecular meshwork). D.I. 292-35, Tanna Glaukos Rep. ¶ 144. Dr. Tanna further opined that even if "some aqueous may enter Schlemm's canal through the windows of the Hydrus, once *within* Schlemm's canal, it does not result in the type of axial flow that shoots across Schlemm's canal that [Glaukos' expert] hypothesizes." *Id.* Dr. Tanna did not admit that fluid does in fact flow through the Hydrus' windows. Rather, Dr. Tanna provided an alternative opinion that Hydrus would not infringe even if there was fluid flow through the windows. *Id.*

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ALCON'S ADDITIONAL CONCISE STATEMENT OF FACTS IN SUPPORT OF ALCON'S ANSWERING BRIEF TO SIGHT'S MOTION NO. 2

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I. ALCON'S ADDITIONAL CONCISE STATEMENT OF FACTS IN SUPPORT OF ALCON'S ANSWERING BRIEF TO SIGHT'S MOTION NO. 2

1. Hydrus is a bypass device that includes an inlet that bypasses the trabecular meshwork. D.I. 298-14, Downs Op. Rep. ¶ 376 ("Hydrus bypasses the [trabecular meshwork] through the inlet of the device to allow fluid to pass from the anterior chamber to Schlemm's canal"); D.I. 298-19, Iwach Reb. Rep ¶ 117 ("Hydrus provides a bypass to the trabecular meshwork via the inlet"); Ex. 1, Iwach Rpl. Rep. ¶ 71 ("In my opinion, it is unlikely that much, if any, aqueous flows across the trabecular meshwork once the Hydrus has been inserted into Schlemm's canal (because the stent bypasses the trabecular meshwork)"); D.I. 298-23, 9/22 Downs Tr. 78:4-6 ("Q: Part of [Hydrus] device is – provides a bypass, right? A: Yes. One Aspect").

2. When bypass devices are implanted at least partially within Schlemm's canal, the pressure between the anterior chamber and the lumen of Schlemm's canal is equalized. Ex. 38 (IVANTIS_SS_00026860) ("If a patent channel could be conceived through the trabecular meshwork (a trabecular bypass), the aqueous would have the shortest path to enter the Schlemm's canal…Hence the trabecular bypass provides the lowest resistance path into Schlemm's canal, therefore allowing the bulk of aqueous to enter the canal…."); *id.* ("Recently a new technique has emerged where a single silicone tube was implanted in autopsy eyes 7 and in patients 8 to connect the anterior chamber to Schlemm's canal. The IOP was reduced because the aqueous humor can directly enter Schlemm's canal by unidirectionally bypassing the highly resistant trabecular meshwork and draining out of the less resistant collector channels."); D.I. 298-19, Iwach Reb. Rep. ¶¶ 109, 114 ("bypass stents are typically implanted to *bypass* the trabecular meshwork because the trabecular meshwork is a known area of resistance for aqueous humor (*i.e.*, prevents or limits outflow) in glaucomatous patients" and therefore "it is unlikely that much, if any, aqueous humor flows across the trabecular meshwork into Schlemm's canal after Hydrus is implanted"); Ex. 1,

Iwach Rpl. Rep. ¶ 171 (opining that [redacted] and noting that "[m]ultiple studies modeling the effects of bypass stents implanted in Schlemm's canal have found that the pressure differential between the stented canal near the bypass and the stented canal at a distal portion of the device is, theoretically, extremely minor"); ¶ 172 (noting that Dr. Downs concedes that inserting a bypass stent "lowers the pressure differential between the anterior chamber and Schlemm's canal from a diseased, non-bypassed state"); D.I. 298-15, Downs Reb. Rep. ¶ 128 ("The devices disclosed by Gharib and Gharib-239 are trabecular bypass shunts…. Thus, the express purpose of the device disclosed in Gharib and Gharib-239 is to re-route fluid ***through a conduit that bypasses*** the trabecular meshwork."); ¶ 168 (opining that a POSA would have "knowledge of the general laws of fluid dynamics, which dictate that fluid will follow the path of least resistance"); ¶ 170 (describing prior expert analysis that concluded that pressure in Schlemm's canal would equal pressure in the eye when a bypass device is inserted into Schlemm's canal because the bypass effectively connects the anterior chamber of the eye to Schlemm's canal near the bypass stent); ¶ 172 (describing prior art device, iStent, that has a bypass inlet and explaining when iStent is implanted "the transmural pressure and flow across the trabecular meshwork would also be zero, regardless of whether fenestrations of any size are present or not"); ¶ 173 (explaining that when Hydrus is implanted, fluid would flow though the inlet and "pressure between the anterior chamber and the area of Schlemm's canal around the outlet of the bypass would equalize almost instantaneously"), ¶ 262 ("POSA would understand that once an unobstructed bypass was implanted between the anterior chamber and Schlemm's canal, fluid would flow through the bypass and the pressure between the anterior chamber and Schlemm's canal would equalize almost instantaneously."); Ex. 36 (IVANTIS_SS_00344684) at 689-690 (finding "likely no significant difference in the efficacy of

the 8-mm microstent as compared to its prior 15-mm version," suggesting fluid flows through Hydrus bypass inlet instead of through the trabecular meshwork); D.I. 292-31 (SGHT0170310) (confocal microscopy images showing that "[i]n the Hydrus scaffold regions, the majority of tracer appears to bypass the TM and directly enter SC and into more [episcleral veins] EVs via multiple [collector channels] CCs"); D.I. 298-23, 9/22 Downs Tr. 226:13-23 (when Hydrus is implanted, "the pressures at that first window in Schlemm's canal are going to be very similar to the pressures [in the eye]").

3. There is no flow across the trabecular meshwork if there is no pressure gradient between the anterior chamber and the lumen of Schlemm's canal. D.I. 298-15, Downs Reb. Rep. ¶ 170 (describing prior expert analysis that concluded that pressure in Schlemm's canal would equal pressure in the eye when a bypass device is inserted into Schlemm's canal because the bypass effectively connects the anterior chamber of the eye to Schlemm's canal near the bypass stent); ¶ 172 (describing prior art device, iStent, that has a bypass inlet and explaining when iStent is implanted "the transmural pressure and flow across the trabecular meshwork would also be zero, regardless of whether fenestrations of any size are present or not"); ¶ 173 (explaining that when Hydrus is implanted, fluid would flow though the inlet and "pressure between the anterior chamber and the area of Schlemm's canal around the outlet of the bypass would equalize almost instantaneously"), ¶ 262 ("POSA would understand that once an unobstructed bypass was implanted between the anterior chamber and Schlemm's canal, fluid would flow through the bypass and the pressure between the anterior chamber and Schlemm's canal would equalize almost instantaneously"); D.I. 298-19, Iwach Reb. Rep. ¶¶ 109, 114 ("bypass stents are typically implanted to *bypass* the trabecular meshwork because the trabecular meshwork is a known area of resistance for aqueous humor (*i.e.*, prevents or limits outflow) in glaucomatous patients" and

therefore "it is unlikely that much, if any, aqueous humor flows across the trabecular meshwork into Schlemm's canal after Hydrus is implanted"); Ex. 36 (IVANTIS_SS_00344684) at 689-690 (study concluding that 15 mm version of Hydrus showed similar efficacy compared to 8 mm version despite having more openings abutting the trabecular meshwork); Ex. 1, Iwach Rpl. Rep. ¶ 171 (opining that [redacted] and noting that "[m]ultiple studies modeling the effects of bypass stents implanted in Schlemm's canal have found that the pressure differential between the stented canal near the bypass and the stented canal at a distal portion of the device is, theoretically, extremely minor").

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Exhibit 3

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	C.A. No. 21-1317-GBW-SRF [redacted]

ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 3

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I. ALCON'S RESPONSE TO SIGHT'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION NO. 3

1. Disputed. In Alcon's initial invalidity contentions, Alcon contended that the iStent was first used publicly ***and/or disclosed*** "at least as early as July 2004." D.I. 292-36 at 8.

2. Undisputed.

3. Undisputed.

4. Disputed. In addition to Bahler and Samuelson, Alcon identified NCT00323284 in their initial invalidity contentions, the publication of an iStent clinical study, which began enrolling patients in June 2005. D.I. 292-38 at 1; Ex. 48, NCT00323284 (https://www.clinicaltrials.gov/study/NCT00323284). Moreover, the following additional evidence of the iStent's public availability was disclosed in Dr. Tanna's Opening Report: Samuelson 2004, the iStent Directions for Use (DFU), and Sherwood. *See* Ex. 51, IVANTIS_SS_00471285, Sherwood (reproduced in color); D.I. 292-39, Samuelson 2004; D.I. 291-40, iStent DFU. Additionally, Alcon identified the additional evidence of iStent's public availability during Sight's expert, Dr. Downs's, deposition: Abstract for a presentation given at the Association for Research in Vision and Ophthalmology Annual Meeting entitled "Co-Existent Open-Angle Glaucoma and Cataract: Treatment by Cataract Surgery and the iStent™ Trabecular Bypass Micro Stent." *See* Ex. 52, IVANTIS_SS_00471290, 9/28 Downs Tr. Ex. 9.

5. Disputed. Dr. Tanna substantively relies on Samuelson 2004 in connection with his opinions that the iStent anticipates and/or renders obvious the claims of the Patents-in-Suit. For example, Dr. Tanna opines that the iStent anticipates and/or renders obvious the limitation "a support implantable circumferentially within Schlemm's canal and configured to maintain the patency of at least a portion thereof," in claim 1 of the '443 Patent in part due to Samuelson 2004's description of the benefits of the iStent's "circumferential implantation procedure." D.I. 298-17,

Tanna Op. Rep. at ¶ 412. Dr. Tanna further relies on this disclosure in support of his opinions that the iStent anticipates and/or renders obvious each of the other Patents-in-Suit. *Id*. at ¶¶ 1069, 1195. Moreover, Dr. Tanna cited Samuelson 2004 and the following publications describing the iStent and evidencing its public availability in addition to Samuelson2 and the iStent Directions for Use: (1) Samuelson 2004, *see* D.I. 298-18, Tanna Reply Rep. at ¶ 321, (2) Bahler, *see e.g.,* D.I. 298-17, Tanna Op. Rep. at ¶¶ 151, 157, 239, 340, 412–414, 418, 430, 432, 435, 438, 440, 443, 450, 454, 456, 471, 1242; Ex. 5, Tanna Reb. Rep. at ¶ 24 n. 7; D.I. 298-18, Tanna Reply Rep. at ¶ 42, 81, 119, 181, 321, and (3) Sherwood, *see, e.g.,* D.I. 298-17, Tanna Op. Rep. at ¶¶ 313-315, 333, 415, 435, 468-469, 1131, 1229, 1242; Ex. 5, Tanna Reb. Rep. at ¶¶ 18, 32; D.I. 298-18, Tanna Reply Rep. at ¶¶ 14, 155, 204, 292 n. 12, 298.

6. Undisputed.

7. Undisputed, but immaterial. Determining validity in light of an alleged sale involves "determining whether a sale is truly a 'sale' within the meaning of 35 U.S.C. § 102(b), a question of law based on underlying facts." *See Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1376 (Fed. Cir. 2003). Dr. Tanna is not a lawyer and does not opine on what constitutes a "sale," as a legal matter, under § 102(b). *See* Ex. 6, Tanna Op. Rep. Ex. 1.

8. Undisputed, but immaterial. Determining validity in light of an alleged sale involves "determining whether a sale is truly a 'sale' within the meaning of 35 U.S.C. § 102(b), a question of law based on underlying facts." *See Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1376 (Fed. Cir. 2003). Dr. Tanna is not a lawyer and does not opine on what constitutes a "sale," as a legal matter, under § 102(b). *See* Ex. 6, Tanna Op. Rep. Ex. 1.

9. Disputed. Dr. Tanna did not admit that there were no public uses of the iStent before June 26, 2006. Dr. Tanna is not a lawyer and was unfamiliar with the legal term of art

"experimental use" used in the cited question. Indeed, Sight ignores the bulk of Dr. Tanna's testimony, which makes clear that he testified the iStent ***was*** publicly available prior to June 2006. *See* Ex. 22, Tanna Tr. 258:1–8 (Q. Is it your opinion that the iStent device itself was publicly available before 2006? A. It was publicly available in that its physical characteristics were widely known, as described in Bahler and as described at many meetings. And it was available for clinical trials.); s*ee also id.* at 58:12–59:3 ("[W]e knew a lot about the iStent prior to FDA approval…. There may have been promotional-type materials that people were using to show what the iStent looked like.… [Glaukos] was very proud about what was developing and definitely was talking about it. And at national meetings, there were people who were giving lectures about the device."); *id.* at 80:3–6 ("In 2006 I showed residents the iStent and told them about iStent implantation as an ab-interno approach that was on the horizon."); *id*. at 238:10–16 ("There were probably 25 different centers that were participating in the clinical trial for iStent. And so there were a lot of people who knew and were talking about iStent, showing pictures of it, showing video of it. And so there was no secret of iStent in 2006."); D.I. 298-17, Tanna Op. Rep. at ¶ 92 ("I understand the iStent to be prior art to the Patents-in-Suit because it was publicly available more than one year before the earliest asserted priority date for any of the Asserted Claims."). The iStent was widely available for clinical trials, details about the iStent, including images and exact dimensions, were published in articles, and the device was described at industry presentations, all evidencing that the physicians who were given the iStent prior to June 2006 were not subject to confidentiality provisions or, if they were, Glaukos did not enforce them. *See* Ex. 51, IVANTIS_SS_00471285, Sherwood; Ex. 52, IVANTIS_SS_00471290, Downs Tr. Ex. 9; D.I. 292-39; D.I. 292-40; D.I. 292-41; D.I. 298-41.

10. Disputed. Dr. Tanna is not a lawyer and did not admit that availability for clinical trials does not equate to public availability, **as a legal matter**. *See* Ex. 6, Tanna Op. Rep. Ex. 1; *Netscape Commc'n Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002) ("Whether a patent is invalid for a public use or sale is a question of law based on underlying facts."). As Dr. Tanna's answer immediately prior—which Sight ignores—makes clear, Dr. Tanna testified that the iStent was publicly available before June 2006 in part due to its "availabil[ity] for clinical trials." Ex. 22, Tanna Tr. 258:1–8 (Q. Is it your opinion that the iStent device itself was publicly available before 2006? A. It was publicly available in that its physical characteristics were widely known, as described in Bahler and as described at many meetings. And it was available for clinical trials.)

11. Disputed. Dr. Tanna testified only that he did not have personal knowledge of whether the iStent DFU were available before June 26, 2006. But Dr. Tanna further testified that the evidence showed that the DFU would have been available before June 26, 2006 because they would have been available to surgeons conducting clinical trials "***as early as 2004.***" *See* Ex. 22, Tanna Tr. 257:18–25 ("And regarding the instructions, Dr. Downs contends that they're not prior art because they were not published or available until after 2006, June 22nd, 2006. But the instructions for use would have been available to surgeons for the clinical trials. And that would have been as early as 2004."). Bahler and Sherwood both include language that mirrors the directions for use further indicating their availability to surgeons. *Compare,* Ex. 51, IVANTIS_SS_00471285, Sherwood, at 285 (The iStent is inserted through a cornea incision, allows the aqueous humor to flow towards it's natural physiologic pathway (the episcleral drainage system) by bypassing the trabecular meshwork and safety and efficacy has not yet been established for more than one stent.), D.I. 298-41 at 870 (Insertion technique requires "gonioscopy and use of a modified four-pronged vitreoretinal forceps to grasp the inlet portion of the stent and insert

through a corneal paracentesis.") *with* D.I. 292-41 at 1, 4, 6; *see also* Ex. 15, 9/28 Downs Tr. 189:7–190:7 (admitting figure in Bahler has same curvature as DFU figure).

12. Disputed. While Dr. Tanna does not dispute that Samuelson2 itself is not prior art, he testified that "what's really important [in Samuelson2] is that the clinical trial on which this was based on was started in I believe 2005 and was listed in clinicaltrials.gov at around that time. Maybe before that time," Ex. 22, Tanna Tr. 233:9–13, and this supports his opinion that the iStent was known and/or publicly available before June 26, 2006. *See* D.I. 298-17 at ¶1242; D.I. 298-18 at ¶322.

13. Disputed. The results of iStent clinical trials were publicly available prior to June 26, 2006. Interim results of an iStent clinical trial that began in 2003 were published in an abstract and presented on at the Annual Meeting of the Association for Research and Vision in Ophthalmology in May 2005. *See* Ex. 52, IVANTIS_SS_00471290, Downs Tr. Ex. 9; *See also* Ex. 53, IVANTIS_SS_00471292, Spiegel 2008 (publishing results of iStent trial and noting data was presented in part at ARVO 2005); Ex. 49, NCT00326014 (https://www.clinicaltrials.gov/study/NCT00326014); *see also* Ex. 22, Tanna Tr. 59:8–11 ("So at ARVO in 2005 there – there were -- there was at least one presentation on iStent."). Further, Bahler, published in 2004, includes results of a Phase I iStent clinical trial that was presented on in March 2003 and describes results of their own iStent study (including a picture and detailed description of the iStent while doing so). *See* D.I. 298-41. Sherwood, published in March 2006, similarly describes the results of an iStent clinical study published in 2005 and includes photographs of the device. *See* Ex. 51, IVANTIS_SS_00471285, Sherwood, at 286.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	C.A. No. 21-1317-GBW-SRF [redacted]

ALCON'S ADDITIONAL CONCISE STATEMENT OF FACTS IN SUPPORT OF ALCON'S ANSWERING BRIEF TO SIGHT'S MOTION NO. 3

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I. ALCON'S ADDITIONAL CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS ANSWERING BRIEF TO SIGHT'S MOTION NO. 3

1. In response to Alcon's Interrogatory No. 8, asking to describe "the basis of any contentions that the cited Prior Art…does not constitute Prior Art," Plaintiff did not include any contention that the iStent device is not prior art. *See* D.I. 298-65, 5/25/2023 Sight's 2nd Supp. Resp. Rog. 8.

2. Dr. Parrish opines that iStent clinical trials began as early as 2003. *See* D.I. 295-5, Parrish Reb. Rep. at ¶60 ("I searched clinicaltrials.gov for iStent clinical trial that were started prior to June 6, 2006, and identified three completed studies, which had the following start and completion dates: NCT00326014 (April 2003-March 2008); NCT00323284 (June 2005 to March 2010) and NCT00326066 (February 2005 to May 2013).") (citations omitted).

3. Dr. Parrish testified that surgeons involved in clinical trials of iStent were provided instructions on how to use the device. *See* Ex. 21, Parrish Tr. 162:7–11 (Q. You mentioned in your answer that surgeons involved in the clinical trials of iStent were provided instructions on how to use the device, is that right? A. That is my understanding, yes.).

4. Paul Badawi testified that he was aware of the iStent prior to his conception of the alleged inventions in June 2006. *See* Ex. 12, 6/23 Badawi Tr. 41:14–24 ("Q. Were you aware, you or your brother, aware at the time of this conversation in 2006, of any other implants or stents that were being delivered into Schlemm's canal? A. I believe we were aware of another product called iStent. I think they were -- I think they were in clinical trials, maybe early studies. Because I think they started in like maybe early 2000s. So probably spent a few years in development and then around that time, they probably would have been doing some early clinical work. Q. And that's the iStent by Glaukos? A. Correct.")

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